IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, ex rel. SARAH BEHNKE,	:	
	:	**CIVIL ACTION NO.**
Plaintiffs,	:	**2:14-cv-00824-MSG**
	:	
v.	:	**[PROPOSED] SECOND**
	:	**AMENDED COMPLAINT**
CVS CAREMARK CORPORATION, CAREMARK Rx, LLC (f/k/a CAREMARK Rx, INC.), CAREMARKPCS HEALTH LLC, and CAREMARK PART D SERVICES, LLC,	:	**JURY TRIAL DEMANDED**
	:	**FILED UNDER SEAL**
Defendants	:	
	:	

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I. INTRODUCTION

Qui Tam Plaintiff/Relator Sarah Behnke, through her counsel, Berger & Montague, P.C. and Shepherd Finkelman Miller & Shah, LLP, on behalf of the United States of America, brings her Complaint against Defendants CVS Caremark Corporation, Caremark Rx, LLC (f/k/a Caremark Rx, Inc.), CaremarkPCS Health LLC, and Caremark Part D Services, LLC, and alleges based upon her own direct and independent knowledge and investigation, except where specifically stated upon information and belief:

1. This is an action to recover damages and civil penalties on behalf of the United States of America, arising from false and/or fraudulent records, statements and claims made or caused to be made or presented by CVS Caremark Corporation, Caremark Rx, LLC (f/k/a Caremark Rx, Inc.), CaremarkPCS Health LLC and Caremark Part D Services, LLC (collectively referred to as "Caremark" or "Defendants") and/or their agents, predecessors, successors, and employees in violation of the Federal False Claims Act, 31 U.S.C. § 3729 *et seq*., as amended ("the FCA" or "the Act").. References in this complaint to Caremark include CVS Caremark Corporation and its subsidiaries and affiliates to the extent they are involved in the conduct.

2. The Caremark defendants, in their capacity as a Pharmacy Benefits Manager ("PBM") for several Medicare Part D Sponsors, including their affiliate SilverScript Insurance Co. ("SilverScript"), intentionally, systematically, and recklessly caused the submission of false or fraudulent Medicare Part D actual drug costs, negotiated drug prices, and prescription drug event ("PDE") data to the Centers for Medicare and Medicaid Services ("CMS") since 2010.

3. In addition to the false and fraudulent claims, prices and statements by or through SilverScript, the Caremark defendants caused non-party Aetna, Inc. (or its affiliates) (hereafter referred to as "Aetna") to make or present false claims and statements to CMS. Pursuant to a

multi-year contract, Caremark is the PBM for Aetna's Medicare Part D business, as well as for Aetna's commercial lines of business.

4. As a direct result of Defendants' fraudulent, improper and illegal practices, Federal Government health insurance programs including, but not limited to, Medicare Part D, have been caused and continue to:

a) pay increased subsidies to Aetna's Medicare Part D Plans and the SilverScript Medicare Part D Plans through direct advance monthly payments; reinsurance subsidies; low-income cost-sharing subsidies (or grants for low-income Part D individuals received in lieu of low-income subsidies); risk-sharing arrangements; and year-end retroactive adjustments and reconciliations; and

b) enter into contracts with the Defendants as providers of Part D services, whether as a Sponsor or PBM, including agreements that are necessary for Part D providers to submit claims or data to CMS and/or to receive payments related to the Medicare Part D program.

5. As a direct and foreseeable result of the Defendants' improper and fraudulent practices, federal and state health insurance programs, including but not limited to, Medicare and Medicaid, have been impacted by Defendants' submission of false prices by virtue of the states' contributions to low-income cost subsidies.

6. Plaintiff seeks to recover damages and penalties on behalf of the United States arising from Defendants' making or causing to be made false or fraudulent records, statements and/or claims in connection with their knowing violations of the Medicare Part D Program reporting, reconciliation and claims submissions requirements.

II. THE PARTIES

A. Relator/Plaintiff

7. Plaintiff/Relator Sarah Behnke is a resident of the State of Kentucky and a citizen of the United States.

8. Relator Behnke is a graduate of the University of California at Berkeley, with a B.A. in applied mathematics. She is a Fellow of the Society of Actuaries (FSA), a professional designation that is achieved only after the successful completion of more than ten rigorous examinations. Ms. Behnke is also a member of the American Academy of Actuaries (MAAA). Ms. Behnke has worked for three major Part D plan sponsors, including Humana, in the area of Medicare Part D Plan pricing and reimbursement since the program became effective in 2006. At the time of filing this action, she was the Senior Actuary/Head Actuary Medicare Part D for Aetna, Inc. Relator has extensive experience with drug pricing for Part D Plans, analysis of pharmacy data, risk sharing agreements, Direct and Indirect Remuneration Reporting ("DIR") and Part D regulations relating to low income subsidies, risk sharing, reinsurance and Part D bids. She is uniquely qualified to bring this action on behalf of the United States.

B. Defendants

1. Defendant CVS Caremark Corporation

9. Defendant CVS Caremark Corporation (hereafter "CVS Caremark") is incorporated under the laws of the State of Delaware, and headquartered at One CVS Drive, Woonsocket, Rhode Island 02895.

10. CVS Caremark Rx, LLC is a subsidiary of CVS Caremark

11. CVS Caremark has reported to the public that since at least 2007, it and its subsidiaries have been the largest provider of prescription and related healthcare services in the United States, having filled or managed more than one billion prescriptions since that time.

12. In its pharmacy services business, CVS Caremark offers a full range of pharmacy benefit management ("PBM") services. The PBM business generates revenues for CVS Caremark from the performance of services for which it receives certain fees. These PBM services include mail order pharmacy services, specialty pharmacy services, plan design, administration, pharmacy network contracting, and claims processing. At the time of filing, CVS Caremark had 26% of the PBM market in the United States and the CVS Caremark PBM business served approximately 3,150,000 Medicare members.

2. CVS Caremark Entities Participating in Medicare Part D Program

13. Currently, CVS Caremark participates in the Medicare Part D prescription drug program in several significant ways. Since 2006, CVS Caremark has provided Part D PBM services to CVS Caremark's clients' Part D programs through several subsidiaries including: Caremark LLC; CaremarkPCS Health, LLC; CVS Caremark Part D Services, LLC; and Caremark RxAmerica, LLC.

14. Since 2006, subsidiaries or affiliates of CVS Caremark have served as Medicare Prescription Drug Plan ("PDP") Sponsor that contracts with Medicare to provide prescription drug benefits in all 50 states, the District of Columbia, and Puerto Rico.

15. The Defendants participate in the Federal Government's Medicare Part D Program as pharmacy benefit managers (PBM). CVS Caremark's net revenue includes both Part D Payments received from CMS as well as payments received from Part D Sponsors related to CVS Caremark's subsidiaries' Part D PBM Services.

16. In addition, subsidiaries of CVS Caremark operates thousands of retail pharmacies under the names CVS or Longs Drug Store, as well as mail order and specialty pharmacies that

process Part D prescriptions and dispense Part D drugs to Medicare beneficiaries, including to beneficiaries enrolled in Aetna's and Caremark's own Part D programs.

17. SilverScript Insurance Company ("SilverScript"), is a corporation organized under the laws of Tennessee. It is a subsidiary of CVS Caremark.

18. SilverScript is a Medicare Part D Sponsor that since 2006 has contracted with Medicare and has provided Medicare Part D benefits under prescription drug plans in all 50 states, the District of Columbia, and Puerto Rico.

3. Defendant CVS Caremark's PBM Subsidiaries

19. Defendant Caremark Rx, LLC (f/k/a Caremark Rx, Inc.) (hereafter "Caremark Rx") is one of the largest pharmaceutical services companies in the United States. It is incorporated under the laws of the State of Delaware, with its principal executive offices located in Woonsocket, Rhode Island. Caremark Rx is the parent of CVS Caremark's pharmacy services subsidiaries that provide pharmacy benefit management services.

20. Caremark Rx's pharmaceutical services are referred to as pharmacy benefit management services, and include the provision of drug benefits to eligible beneficiaries under the Federal Government's Medicare Part D Program.

21. CaremarkPCSHealth LLC ("CaremarkPCS Health") is a subsidiary of Caremark Rx. CaremarkPCS Health is a PBM (pharmacy benefit manager) and provides PBM services to its clients that have qualified as Medicare Part D Prescription Drug Plans, including Aetna.

22. Defendant Caremark Part D Services, LLC is a CVS Caremark subsidiary that provides PBM services to SilverScript, among other Part D Plans.

23. CVS Caremark participates in the administration of the Medicare Part D Drug Benefit through Caremark Rx. Caremark Rx's PBM services are provided to its health plan clients and other clients that have qualified as PDPs.

24. Prescriptions managed by the Caremark defendants for Part D plan sponsors, whether filled at one of CVS Caremark's own mail service pharmacies or through its retail pharmacy network, are processed and documented by the Caremark defendants.

III. JURISDICTION AND VENUE

25. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. § 3732.

26. This Court has personal jurisdiction and venue over Defendants pursuant to 28 U.S.C. § 1391(b) and U.S.C. § 3732(a) because that section authorizes nationwide service of process and because the Defendants have minimum contacts with the United States. Moreover, the Defendants can be found in, and reside and transact business in, this District.

27. Venue is also proper in this District pursuant to U.S.C. § 3731(a) because CVS Caremark Corporation, Caremark Rx, LLC (f/k/a Caremark Rx, Inc.), CaremarkPCS Health LLC, and Caremark Part D Services, LLC can be found in, and conduct business in this District.

IV. THE MEDICARE PART D PROGRAM

A. Prescription Drug Coverage

28. The Medicare Part D Program provides beneficiaries with assistance in paying for outpatient prescription drugs. The outpatient prescription drug benefit was added to Medicare by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. 108-173 (Dec. 8, 2003), 42 U.S.C. § 1395w-101 *et seq*. (2004 supplement), 42 C.F.R. § 423.506.

29. An individual is eligible to enroll in part D if he or she is entitled to Medicare benefits under Part A or enrolled under Part B, 42 U.S.C. § 1395w-101(a)(3)(A); 42 C.F.R. § 423.30(a).

B. Operation of the Medicare Part D System

1. Part D Plan Sponsor

30. Unlike coverage in Medicare Parts A and B, Part D coverage is not provided within the traditional Medicare program. Instead, the MMA established Part D as a voluntary, private-market-based program that was based on private plans providing coverage and bearing some of the financial risk for drug costs. Medicare beneficiaries must affirmatively enroll in one of the many hundreds of Part D Plans offered by private companies. *See* MMA, Sections 1102, 1860D-1 through 1860D-42, and 1871 of the Social Security Act; 42 U.S.C. §§ 1302, 1395w-101 through 1395w-152, and 1395hh.

31. Part D benefits are provided by either a Part D Plan Sponsor, a Medicare Advantage organization that offers a Medicare Advantage-Part D plan, a PACE organization offering a PACE plan including qualified drug coverage or a cost plan offering qualified prescription drug coverage that has entered into a contract with Medicare. Part D Plan Sponsors offer a prescription drug plan ("PDP"). 42 C.F.R. § 423.4. References in this Complaint to "Part D business" include all of these types of plans or coverages.

32. "Prescription drug plan" or "PDP" means "prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in [42 C.F.R.] § 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the contract requirements under subpart K of [Part 423]." 42 C.F.R. § 423.4.

33. Aetna Life Insurance Company, at the time of filing, was a Part D Plan Sponsor that offers Part D plans through various affiliates, including Aetna Health Management LLC. A Part D Plan Sponsor agrees to comply with the requirements and standards of Part D and all the terms and conditions of payment. Section 1860D-12, 42 U.S.C. § 423.503(b). Aetna as the Part D

Plan Sponsor also expressly agrees to provide CMS with the information CMS determines is necessary to carry out payment provisions. 42 C.F.R. § 423.505(b)(8) and (9).

34. A Part D Plan Sponsor, in contracting with CMS, also expressly "agrees to comply with Federal laws and regulations designed to prevent fraud, waste, and abuse, including but not limited to, applicable provisions of Federal criminal law [and] the False Claims Act (31 U.S.C. §§ 3729 *et seq*.)." 42 C.F.R. § 423.505(h)(1).

35. In order to receive Part D funds from CMS, Part D Sponsors, their authorized agents, employees and contractors are required to comply with all applicable Federal laws and regulations, as well as CMS instructions. 42 U.S.C. § 1860D-12(b)(1); 42 C.F.R. § 505(i)(4)(v).

36. To qualify for Part D payments from CMS, before each plan year, a Part D Sponsor must submit a bid, certified by an actuary, for each Part D Plan it will offer. 42 C.F.R. § 423.265. The bid contains a per member per month ("PMPM") cost estimate to provide Part D benefits to an average Medicare beneficiary in a particular geographic area. From those Part D Plan bids, CMS calculates nationwide and regional benchmarks that represent an average PMPM cost. The bid is used to set the premium for a Part D Plan. If the Part D Plan Sponsor's bid exceeds the benchmark, the Plan Member must pay the difference.

37. Each Part D sponsor receives a direct subsidy from CMS in the form of advance monthly payments equal to the Part D plan's standardized bid, which is risk-adjusted for health status, minus the monthly beneficiary premium, estimated reinsurance subsidies for catastrophic coverage, and estimated low-income subsidies. 42 C.F.R. §§ 423.315, 423.329.

38. In the year following each benefit year, CMS reconciles a PDP Sponsor's actual prescription drug costs as derived from its PDE records against the Sponsor's bid.

39. If a PDP Sponsor's actual costs exceed the estimated costs, it may be able to recoup some of its losses through a risk-sharing arrangement with CMS. Conversely, if a Part D Plan Sponsor's estimated costs exceed its actual costs, the Sponsor may have to pay back some of its estimated payments to CMS.

40. Sections 1860D-15(c)(1)(C) and (d)(2) of the MMA require Sponsors to submit data and information necessary for CMS to carry out payment provisions. For every prescription filled, the Sponsor prepares and submits a Prescription Drug Event (PDE) record to CMS (described in detail in section IV.B.5).

41. Accordingly, all contracts between Part D Sponsors and CMS contain the following term: the Part D Sponsor must agree to "provide CMS with the information CMS determines is necessary to carry out payment provisions in subpart G of this Part." 42 C.F.R. § 423.505(b)(9).

42. The PDE record contains prescription drug cost and payment data that enables CMS to make payments to PDPs and otherwise administer the Part D benefit.

43. The Part D Sponsor is required to make several significant and material express certifications to CMS regarding its submission of Part D data used for payment, as described below (section IV.B.6).

2. Part D Process – Adjudicating Claims for Beneficiaries

44. Most Medicare beneficiaries who elect Part D coverage are responsible for certain costs, which may include a monthly premium, an annual deductible, and/or co-pays. Once a beneficiary's drug costs have reached a designated threshold, the beneficiary pays the entire drug cost until a higher, catastrophic level amount is reached, at which point CMS picks up the bulk of the payments. The phase in which the beneficiary pays his or her own costs is referred to as the coverage gap or, more colloquially, the donut hole.

45. After receiving a prescription from his or her doctor, a Plan beneficiary must get the prescription filled, often by going to a retail pharmacy and presenting the prescription to the pharmacist (or by submitting a prescription to a mail order pharmacy).

46. The pharmacy receives the prescription and participant's information, and then submits required data elements to the Plan Sponsor or its Pharmacy Benefits Manager[1] to confirm Medicare Part D enrollment and identify co-pays. This typically takes place via real-time data transmissions between the pharmacy and the PBM.

47. If the claim for the prescription is not rejected, the pharmacy receives payment authorization and co-pay information and dispenses the prescription to the Part D beneficiary. The beneficiary pays the co-pay to the pharmacy and receives the prescription. At the time of the initial data submission, the pharmacy transmits certain data elements specified by contract between the pharmacy and the PBM. These data elements include, among other things, the beneficiary information and drug information.

48. Once the PBM receives that data from the pharmacy, it submits the claim data to CMS, either directly or through the Plan Sponsor, via a Prescription Drug Event ("PDE") record that includes the drug price.

49. The Plan Sponsor is required to also submit other data to CMS, *i.e.*, bid submission data, costs for risk corridor and reinsurance information, and data for price comparison. *See, e.g.*, CMS Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE), http://www.cms.hhs.gov/DrugCoverageClaimsData/RxDrugEventDataGuidance.asp#TopOfPage, April 27, 2006, 42 C.F.R. § 423.505(k).

[1] References hereafter will assume that the Plan Sponsor utilizes a PBM.

50. Part D Sponsors are also required to submit other information to CMS regarding costs of providing Part D coverage, *i.e.*, administrative costs, rebates, and other information.

3. CMS Part D Payments

51. During each benefit year, CMS pays a PDP Sponsor, such as Aetna, estimated payments, in advance, on a monthly basis. These direct subsidy payments are equal to Aetna's standardized bid adjusted for health status minus the monthly beneficiary premium, estimated reinsurance subsidies for catastrophic coverage, and estimated low income subsidies. 42 C.F.R. §§ 423.315, 423.329.

52. CMS's payments of premiums and cost sharing subsidies on behalf of certain low income individuals eligible for subsidies as provided for in 42 C.F.R. § 423.780 and § 423.782 are called "Low Income Cost Sharing Subsidies" (or "LICS").

53. CMS's payment for the Government's share of drug costs for beneficiaries who have reached catastrophic coverage is called the reinsurance subsidy.

54. As an express condition of payment by CMS, 42 U.S.C. § 1395w-115d(2)(A), Subsidies for Part D Eligible Individuals for Qualified Prescription Drug Coverage, provides that payments to a PDP sponsor are conditioned upon the furnishing, in a form and manner specified by the Secretary of the Department of Health and Human Services, any such information as may be required to carry out the provisions of that section, including those for the calculation of reinsurance and risk sharing. *See also*, DIR Reporting Requirements.

55. Thus, CMS payments to a Part D Sponsor are expressly conditioned upon the Sponsor providing "information to CMS that is necessary to carry out this subpart, or as required by law." 42 C.F.R. § 423.322(a).

56. Beginning in at least 2010, among other things, PDP Sponsors were required to report to CMS the aggregate amount and type of rebates, discounts, or price concessions, excluding

bona fide service fees that the PBM negotiates that are attributable to patient utilization, and the aggregate amount of the rebates, discounts or price concessions that are passed through to the Plan Sponsor, and the aggregate amount of the difference between the amount the health benefits plan pays to the PBM and the amount the PBM pays retail pharmacies, 42 U.S.C. Sec 1320b-23(b).

4. CMS's Payments are Required to be based on the Actual Cost of a Drug, Meaning the Drug Price Ultimately Received by the Pharmacy

57. Negotiated prices are the payment amounts pharmacies receive from Part D Plan Sponsors (directly or indirectly through a PBM) for covered Part D drugs dispensed to plan enrollees. CMS' payments to Part D Plans are based on the reporting of "negotiated prices" (through PDE reporting) that are actually paid and are then offset by any other price concessions (which are reported in the aggregate through the separate annual DIR reporting process).

58. CMS' regulations dictate how to report the total cost of a drug on the PDE record. For a covered drug, this cost is referred to as "gross covered drug cost." On the PDE record, there are detail cost fields and summary cost fields that report the gross drug cost. These fields distinguish the cost of the drug itself from any dispensing fee or applicable sales tax and they identify drug costs that are eligible for reinsurance payment. http://www.csscoperations.com/internet/Cssc.nsf/files/PDEParticipantGuide%20cameraready%20081811.pdf/$FIle/PDEParticipantGuide%20cameraready%20081811.pdf

59. Under 42 CFR § 423.308, "'*Gross covered prescription drug costs*' mean those actually paid costs incurred under a Part D plan, excluding administrative costs, but including dispensing fees, during the coverage year." They [include] the following: (1) The share of actual costs (as defined by § 423.100 of this part).

60. Under 42 C.F.R. § 423.100, "actual cost" is defined in relevant part as the negotiated price for a Part D drug when the drug is purchased at a network pharmacy.

61. Effective for plan year 2010, the definition of negotiated price for covered Part D drugs means prices "that the Part D Sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity [pharmacy] will receive, in total, for a particular drug." 42 C.F.R. § 423.100.

62. Prior to 2010, the definition of negotiated prices had been "prices for covered Part D drugs that are available to beneficiaries at the point of sale at network pharmacies." Because this allowed PDPs or PBMs to include in their reported prices the difference between what a PBM paid a pharmacy for a particular drug and the higher amount paid by a Plan Sponsor to the PBM under "lock-in price" contracts,[2] the definition was changed in 2009, effective January 1, 2010. CMS required that the difference in price between what a PBM paid the pharmacy and what the Plan Sponsor paid the PBM be considered and excluded as an administrative expense, not a component of drug ingredient cost. 74 Federal Register 1494 at 1505 (Jan. 12, 2009). PBMs could still have lock-in price contracts with Plan Sponsors, but the actual pass-through drug prices had to be reported to CMS. *Id.* at 1508.

63. It was the intention of Congress to exclude risk sharing on administrative expenses. As noted by CMS when the definition of negotiated price in 42 C.F.R. § 423.100 was amended, Part D Sponsors are required to report to CMS "the price ultimately received by the pharmacy or other dispensing provider, also known as the pass-through price." The negotiated or pass through price does "not include any of the administrative fees paid by Part D sponsors to their intermediary contracting organization" or PBM. 74 Fed. Reg. 1494 at 1505 (Jan. 12, 2009).

[2] CMS-4131-FC: The lock-in pricing approach is a contract method by which the Sponsor agrees to pay the PBM a set rate for a particular drug and the PBM negotiates with pharmacies to achieve the best possible price, which may vary from the rate paid to the PBM.

64. As described above, CMS pays Plans for Part D benefits through subsidies and risk sharing, including the "Low-Income Cost Sharing Subsidies" and catastrophic reinsurance payments. These CMS payments are documented and reconciled using PDE data submitted to CMS. CMS "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)," 4.27.2006, page 41, Section 10.1.

65. CMS is required by statute to calculate the reinsurance and risk-sharing payments, "allowable reinsurance costs" and "allowable risk corridor costs," on the basis of costs which have been "actually paid," CMS Final Medicare Part D DIR Reporting Requirement for 2012 at p. 5 (June 7, 2013) ("DIR Reporting").

66. "Actually paid" is defined as:

> *Actually paid* means that the costs must be actually incurred by the Part D sponsor and must be net of any direct or indirect remuneration (including discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred under the Part D plan. Direct and indirect remuneration includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies or similar entities obtained by an intermediary contracting organization with which the Part D plan sponsor has contracted, regardless of whether the intermediary contracting organization retains all or a portion of the direct and indirect remuneration or passes the entire direct and indirect remuneration to the Part D plan sponsor and regardless of the terms of the contract between the plan sponsor and the intermediary contracting organization.

42 C.F.R. § 423.308.

67. "Allowable reinsurance costs" are defined as:

> Allowable reinsurance costs means the subset of gross covered prescription drug costs actually paid that are attributable to basic prescription drug coverage for covered Part D drugs only and that are actually paid by the

> Part D sponsor or by (or on behalf of) an enrollee under the Part D plan. The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any costs determined to be attributable to increased utilization over the standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

42 C.F.R. § 423.308.

68. "Allowable risk corridor costs" means:

> (1) The subset of costs incurred under a Part D plan (not including administrative costs, but including dispensing fees) that are attributable to basic prescription drug coverage only and that are incurred and actually paid by the Part D sponsor to —
>
> (i) A dispensing pharmacy or other dispensing provider (whether directly or through an intermediary contracting organization) under the Part D plan;
>
> (ii) The parties listed in § 423.464(f)(1) of this part with which the Part D sponsor must coordinate benefits, including other Part D plans, as the result of any reconciliation process developed by CMS under § 423.464 of this part; or
>
> (iii) An enrollee (or third party paying on behalf of the enrollee) to indemnify the enrollee when the reimbursement is associated with obtaining drugs under the Part D plan; and
>
> (2) These costs must be based upon imposition of the maximum amount of copayments permitted under § 423.782 of this part. The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any prescription drug coverage costs determined to be attributable to increased utilization over standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

42 C.F.R. § 423.308.

69. Pursuant to 42 C.F.R. § 423.343, after the close of the plan year, CMS is responsible for reconciling the prospective payments to the Part D Sponsor's actual allowable costs to calculate final payments and risk sharing amounts. CMS determines the Plan's actual allowable

costs by relying upon certain data elements submitted by Sponsors in their PDE records. In other words, CMS reconciles payments received by a Part D Plans at the end of the year to determine whether additional funds are due to or from the Part D Plan Sponsor. A Part D Sponsor may also receive other payments from CMS resulting from year end reconciliations and adjustments.

70. CMS specifically relies upon and uses the following Prescription Drug Event ("PDE") cost and payment fields in its year-end reconciliation: gross drug cost above out-of-pocket threshold, gross drug cost below out-of-pocket threshold, low-income cost-sharing subsidy, and covered Part D Plan paid amount. As detailed above, the gross drug cost components are based on the negotiated prices, or pass-through prices, that are required to be reported to CMS on the PDE.

5. Price Reporting to CMS as a Condition of Payment

71. On April 27, 2006, CMS issued "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)", in which CMS identified a set of data elements, PDE data, which are identified as conditions of payment and which are necessary to determine payments to Medicare Part D PDP Sponsors. The Part D Plan must submit a record for each and every dispensing event. "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)," 4.27.2006, pages 5 and 9.

72. The PDE record is a summary record that documents the final adjudication of a dispensing event by a PBM, based upon claims received from pharmacies. "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)," 4.27.2006, page 9.

73. When CMS identified "Data Elements for PDE Records," it clearly stated, and all parties were on notice, that submission of PDE data is an express condition of payment: "In this section, we list the required data elements that must be submitted on PDE records for payment …

This Section defines each data element and its specific potential use for CMS's payment process." CMS "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)," 4.27.2006, page 11, Sec. 2.

74. CMS further described the purpose of the various PDE data elements as follows: "Much of the data, especially in dollar fields, will be used primarily for payment." CMS "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)," 4.27.2006, pages 5-6, Section 1.4.

75. CMS provided that the reporting "requirements apply to all Part D Plans." "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)," 4.27.2006, page 5. Thus, CMS data reporting requirements and instructions apply to all Part D Plans (PDPs), Medicare Advantage Part D Plans (MA-PDs), and any other entity providing Part D benefits.

76. When Part D Sponsors or their PBMs report PDE data to CMS, these data elements include the costs associated with each dispensing event. CMS uses these PDE data elements, in part, to determine the capitated payments (monthly subsidy) paid for each Medicare Part D beneficiary. The Part D Sponsor or PBM is required to submit the cost of the drug actually dispensed to the Part D beneficiary.

77. CMS requires accurate reporting by the Part D Sponsor or PBM of the following three data elements from PDE records to determine costs that qualify for payment under the Medicare benefit: Field 27 (Ingredient Cost Paid), the amount paid to the pharmacy for the drug itself, not including dispensing fees or other costs; Field 30 (Gross Drug Cost Below-Out-of-Pocket Threshold); Field 31 (Gross Drug Cost Above Out-Of-Pocket Threshold). "Updated

Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)," 4.27.2006, pages 14-15.

78. Part D Sponsors are required to make PDE data submissions to CMS at the end of the coverage year (or no later than five months after the close of the year) including PDE records, adjustments and deletions. *See* 42 C.F.R. § 423.308. Part D Sponsors also submit cost reports at the end of the year. 42 C.F.R. § 423.343.

6. Certifications Made by Part D Sponsors

79. Sponsors and their subcontractors, when submitting Part D PDE data to CMS, must certify that all claims are true and accurate. CMS "Prescription Drug Benefit Manual, Chapter 9 -- Part D Program to Control Fraud, Waste, and Abuse," Section 80.1, p. 67, citing 42 C.F.R. § 423.505(k)(3).

80. Thus, CMS's Regulations for the submission of Part D PDE data place the legal risk of submitting invalid Part D claims data squarely with the submitting or generating entity: "CMS requires that any entity that generates [Part D] claims data on behalf of a Sponsor" must both: "certify to CMS the accuracy, completeness, and truthfulness of that data;" and "acknowledge that the data will be used for purposes of obtaining Federal reimbursement." *See* CMS "Prescription Drug Benefit Manual, Chapter 9 -- Part D Program to Control Fraud, Waste, and Abuse," page 16, Section 40-2, citing 42 C.F.R. § 423.505(k)(3).

81. In keeping with the requirements of 42 C.F.R. § 423.505(k)(3) and CMS "Prescription Drug Benefit Manual, Chapter 9 -- Part D Program to Control Fraud, Waste, and Abuse," Section 80.1, p. 67, Sponsors and their subcontractors who submit Part D PDE data to CMS must certify that it is true and accurate.

82. Since January 2006, this express certification of Part D PDE data has been included in CMS's Electronic Data Interchange Agreement ("EDI Agreement") or a similar document. The

EDI Agreement must be executed in order for an eligible organization to submit PDE data electronically to CMS. The Caremark defendants, as Part D PBMs who submit PDE data on behalf of Part D Sponsors, have executed an EDI Agreement with CMS. The certification on the Part D EDI Agreement contains the following (or similar) language:

> By signing below, the eligible organization certifies that each submission of PDE data pursuant to this Agreement will be accurate and complete to the eligible organization's best knowledge, information and belief.

83. Additional certifications submitted by the Part D Sponsor include the following:

a) Certification of Data that Determines Payment:

> As a condition for receiving a monthly payment ... the Part D Plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.

42 C.F.R. § 423.505(k)(1).

b) Part D Sponsor Certification of Claims Data:

> The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) (or for fallback entities, under § 423.871(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement.

42 C.F.R. § 423.505(k)(3).

c) Certification of Bid Submission Information.

> The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information in its bid submission and assumptions related to projected reinsurance and low income cost sharing subsidies is accurate, complete, and truthful and fully conforms to the requirements in § 423.265.

42 C.F.R. § 423.505(k)(4).

> d) Certification of allowable costs for risk corridor and reinsurance information.
>
> The Chief Executive Officer, Chief Financial Officer, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of supporting allowable costs as defined in § 423.308 of this part, including data submitted to CMS regarding direct or indirect remuneration (DIR) that serves to reduce the costs incurred by the Part D sponsor for Part D drugs, is accurate, complete, and truthful and fully conforms to the requirements in § 423.336 and § 423.343 of this part and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

42 C.F.R. § 423.505(k)(5).

84. Particularly relevant here, "If the claims data are generated by a . . . contractor, or subcontractor of a Part D Plan Sponsor, [specifically including a PBM] the contractor or subcontractor must similarly certify (based on best knowledge, information and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement." 42 C. F. R. Sec. 423.505(k)(3)

85. CMS recognizes that the submission of "inaccurate or incomplete prescription drug event (PDE) data" constitutes Part D fraud, waste, or abuse. CMS "Prescription Drug Benefit Manual, Chapter 9 -- Part D Program to Control Fraud, Waste, and Abuse," p. 56.

86. As described below, the Caremark Defendants, in their contract with Aetna, agreed to comply with all applicable law, regulations, and CMS instructions, and acknowledged that claims data and information provide in connection with the contract "are used for the purpose of obtaining federal funds."

87. Contrary to the requirements of 42 C.F.R. § 423.505(k)(3), the Caremark defendants, as a subcontractor, have provided or caused to be provided to the government false

and fraudulent certifications of data accuracy, completeness and truthfulness and acknowledgment that the claims data will be used for the purpose of obtaining federal reimbursement.

V. CVS CAREMARK BOTH REPORTED AND CAUSED THE REPORTING OF FALSE AND INFLATED NEGOTIATED PRICES TO CMS

A. Caremark's Failure to Provide True Negotiated Price Data to Aetna

88. Aetna, at the time of filing, was a Part D Plan Sponsor that had a contract with CMS. Aetna has approximately 750,000 beneficiaries in its Part D Plans and was Caremark's largest unrelated client for PBM services.

89. Aetna Health Management L.L.C., an affiliate of Aetna, entered into a 12-year PBM contract, dated as of July 27, 2010, whereby CaremarkPCS Health L.L.C., Caremark RX L.L.C. and CVS Caremark, agreed to perform certain services for Aetna in connection with Aetna's Part D plan offerings beginning January 1, 2011. Among the services provided by Caremark PSCHealth and Caremark Rx are creating, contracting with, maintaining and administering a network of pharmacies who agree to dispense prescriptions to Aetna Part D beneficiaries, and the negotiation, on behalf of Aetna, of the prices to be paid to the pharmacies for each drug dispensed to an Aetna beneficiary. The Caremark defendants agreed to negotiate the prices with the pharmacies on a pass-through basis, subject to overall rate guarantees. The Caremark defendants further agreed to accurately adjudicate and process for payment claims received on behalf of Aetna Part D plan beneficiaries.

90. CVS Caremark, CaremarkPCS Health and Caremark Rx also agreed to provide drug cost data, including the price paid to the pharmacy for each claim of Aetna Part D beneficiaries (the negotiated price), as required to be submitted to CMS in accordance with 42 C.F.R. § 423.505(b)(8) and (9) and 42 C.F.R. § 423.329(b)(3)(i). The required information is in the set of data known as a Prescription Drug Event ("PDE"), as described above.

91. The prices paid to the pharmacy, the negotiated prices under 42 C.F.R. § 423.100, are also used for other purposes. "Beneficiary cost sharing is a function of the negotiated price, either directly as in coinsurance percentages of the negotiated price, or indirectly, as copayments which are ultimately tied to actuarial equivalence requirements based on negotiated prices." 74 Fed. Reg. 1490 at 1505. In other words, the higher the negotiated price, the higher a beneficiary's out-of-of pocket costs.

92. For purpose of claims adjudication, CaremarkPCS Health provided prices for each claim dispensed to Aetna beneficiaries that CaremarkPCS Health certified were the actual negotiated prices. Aetna included these prices in the PDEs it submitted to CMS for the purpose of getting reimbursed by CMS. The Caremark defendants oversee the creation of the PDE files and review and approve the submission of the PDE files to CMS.

93. Throughout the period from 2011 to the present, the Caremark defendants have reported inaccurate negotiated prices for purposes of reporting to CMS, rendering all claims for payment based on those prices false claims.

94. Under its contract with Aetna, CaremarkPCS Health set a price known as a MAC price for multi-source generic drugs Aetna provides to beneficiaries under its Part D plans. The MAC price is the price Aetna agrees to pay for a prescription for a particular drug. The MAC price is also the price a beneficiary is told is the charge for each specific drug and is the price charged by the pharmacy for the drug when a beneficiary goes to the pharmacy to fill the prescription. This is the price the Caremark defendants reported or caused to be reported as the drug cost on the PDE.

95. Under the contract, CaremarkPCS Health had the ability to change MAC prices. CVS PCSHealth and the Caremark defendants frequently changed the MAC prices throughout the plan year.

96. The Aetna and Caremark contract also contains the following confidential provision, referred to in the industry as a "retail discount guarantee":

MAC and Non-MAC Combined Retail Discount Guarantees for Qualifying Generic Prescriptions at Retail												
Days Supply	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**
1-34	75.00%	75.20%	75.40%	75.60%	75.80%	76.00%	76.20%	76.40%	76.60%	76.80%	77.00%	77.20%
35-83	75.00%	75.20%	75.40%	75.60%	75.80%	76.00%	76.20%	76.40%	76.60%	76.80%	77.00%	77.20%
84+	75.00%	75.20%	75.40%	75.60%	75.80%	76.00%	76.20%	76.40%	76.60%	76.80%	77.00%	77.20%

These percentages listed are discounts off of reported Average Wholesale Prices ("AWP" or "AWPs"), an industry benchmark price. In other words, for example, in 2011, Caremark guaranteed Aetna that Aetna would pay no more in the aggregate than 25% of AWP (the flip side of 75% off AWP) for qualifying generic prescriptions.

97. In addition, the contract sets forth a separate administrative fee to be paid to the Caremark defendants for each paid claim arising from a covered drug dispensed by a retail pharmacy to members under Aetna Part D plans. This fee is in the range of $1.00 per claim.

98. Although there is some question as to whether Aetna's contract with the Caremark defendants required the Caremark entities to negotiate the best prices they can obtain from a pharmacy, or whether the Caremark defendants must actually pass on all discounts they obtain to Aetna (versus merely having agreed to meet certain guaranteed discount amounts and then being permitted to retain any additional savings they could accrue) the Caremark defendants were clearly required to report the actual pass-through or negotiated prices with pharmacies to Aetna for

purposes of reporting to CMS and for purposes of charging Part D beneficiaries for their share of drug payments. The CMS negotiated price regulations are very explicit in providing that even if PBMs continue to have lock-in price contracts with Part D Sponsors, the actual negotiated, pass-through prices to the pharmacy must be reported to CMS. As described in detail below, the Caremark defendants knowingly failed to report true negotiated prices.

99. The Caremark defendants adjusted the MAC prices they set for Aetna's Part D business so that the drug prices for Aetna Part D beneficiaries precisely met, but did not exceed, the retail discount guarantees in the contract between Aetna and Caremark. In other words, the Caremark defendants carefully managed the MAC prices so as to hit the minimum aggregate discount it had guaranteed Aetna, but not to allow Aetna to get the benefit of any lower prices. The arbitrary increases in MAC prices made by the Caremark defendants throughout the year show that they are not reporting true negotiated prices since it is extremely unlikely that the actual prices the Caremark defendants were paying the pharmacies would have increased over time. Market forces in the generic drug industry invariably push generic prices down over time, barring unusual circumstances such as manufacturing issues or ingredient shortages.

100. In September, 2012, the Caremark defendants notified Aetna of an increase in the MAC prices of 229 generic drugs. These drugs represented 59% of the utilization by Aetna's Part D beneficiaries. On average, the increase was 13% for a 30-day supply.

101. Relator did an investigation at that time and discovered that the MAC prices the Caremark defendants had been charging, as well as those they proposed to charge through its new MAC list, were significantly higher than prices being charged by other Part D Plan Sponsors to their beneficiaries for the same drugs. For example, Aetna competitors had prices for lisinoprol 10 mg tablets that ranged from $1.54 to $3.02, but Aetna's price was $4.69.

102. In a November 1, 2012 email regarding the changes to Aetna's Medicare MAC prices, Elana Kinney, Director of Industry Analysis at CVS Caremark, explained that CVS Caremark's proposed Medicare MACs were higher than the commercial MACs because the Medicare MAC prices "were established with consideration to the overall GER targets for each block of business." These GER targets are the guaranteed discount percentages discussed in paragraph 96.

103. As a result of concerns raised by Relator within Aetna, Relator's team did a thorough comparison of the prices for generic drugs that Caremark had allegedly negotiated for Aetna and the prices beneficiaries of Aetna's competitors were paying. Aetna determined that Aetna's prices were as much as 25% to 40% higher than its competitors' prices, or far less competitive than Aetna's size would seem to dictate.

104. In advance of a scheduled telephonic meeting on February 11, 2013, Aetna brought its findings about the drug prices to the attention of the Caremark defendants. Aetna personnel who attended this meeting included Terri Swanson, Head of Medicare Part D, Relator Behnke, Brian Kost, Head of Pharmacy Finance; Howard Crowley, Head Pharmacy Customer Relations and Renwick Elder, Vice President Pharmacy. Employees of the Caremark defendants who attended included James Margiotti, Senior Vice President, Aetna Strategic Business Unit, who is the main Caremark contact with Aetna; Allison Brown, Senior Vice President Underwriting and Actuarial; Brian Januzik, Vice President Actuarial; John Lavin, Senior Vice President Provider Networks; and Beth Paul, Area Vice President for Client Relationship Management.

105. At that meeting and again at a telephonic meeting on February 14, 2013, the Caremark defendants reported that they had basically recreated Aetna's study and they verified that Aetna's analysis of the prices was correct.

106. Ms. Behnke then asked if the Caremark defendants could use this information to negotiate lower pricing with pharmacies or if Caremark had already negotiated discounts similar to what Aetna's competitors had negotiated but were not passing them through to Aetna. In a virtual admission of liability under the Medicare statute and Part D regulations, Allison Brown responded *that the Caremark defendants had negotiated lower prices on Aetna's behalf but it was not required under the contract to provide those prices to Aetna.* As was clearly understood by all parties, however, the prices provided to Aetna were also the prices that Aetna reported to CMS as the negotiated prices.

107. At the February 11 telephonic meeting, CVS Caremark's Allison Brown referred to a "see-saw" effect with CVS Caremark contracts, such that if the Caremark defendants passed better pricing onto Medicare, it would require a concession from CVS Caremark, rather than a concession from the retail pharmacies. The Caremark defendants also stated to the meeting attendees that improving or increasing the discounts Aetna received would adversely impact the Caremark defendants' earnings due to the Caremark defendants retail contracting methodology.

108. This same concept of lower prices that were not being provided to Aetna was referred to a number of times during on-going discussions between Aetna and the Caremark defendants about performing a market check of the drug prices. In a document called Aetna/Caremark CVS Market Check – Briefing Document, prepared which Howard Crowley, Aetna Pharmacy Manager, circulated internally on February 25, 2013, it was noted that the Caremark defendants had "indicated that improving Aetna's Medicare Discounts relative to the current contracted rates will have a direct adverse impact of [sic] CVS Caremark's earnings due to their retail network contracting methodologies."

109. As noted in a March 5, 2013 email written by Relator to the Aetna Medicare team, the Caremark defendants told Aetna "they manage to aggregate discounts that span their Medicare and Commercial clients".

110. In a March 13, 2013 email written by Relator Behnke, which stated that it reflected comments by Aetna's Terri Swanson, Head of Medicare Part D, Behnke wrote: "CVSCM indicated on 2/11 that our competitive analysis would not be helpful in negotiating better rates with pharmacies – but that CVSCM already has secured better rates than they pass along to us. CVSCM indicated that they manage to an aggregate guarantee across lines of business, and thereby passing better rates though [sic] to Aetna would cost CVSCM money. This approach conflicts with the Federal Regulations definition of Pass Through (42 C.F.R. § Sec. 423.308).

111. If the Caremark defendants was accurately reporting the actual prices that were being paid to the pharmacies, however, a change that was achieved in the discount Aetna received would not impact the Caremark defendants' earnings. Rather, if Caremark could have increased Aetna's discount, it would have come from having negotiated lower prices with the pharmacies, which should not have had any impact on the Caremark defendants' bottom line.

112. Although the Caremark defendants and Aetna could have negotiated a contract that permitted the Caremark defendants to charge Aetna a different price (lock-in prices) rather than the pass-through price, in fact the prices the Caremark defendants charged Aetna and the price the Caremark defendants reported for submission to CMS were the same. Accordingly, as stated above, any increase in Aetna's discounts would have only been achievable by garnering greater discounts from the pharmacies, and should not have impacted the Caremark defendant's bottom line since the prices were merely pass-throughs. Caremark's profit for the PBM services is covered through administrative fees, not a mark-up on drug prices. Regardless of the contractual

obligations, moreover, the Caremark defendants were legally required to report those prices to Aetna for submission to CMS. Instead, the Caremark defendants represented that the prices Aetna was paying were the same as the prices the Caremark defendants were paying the pharmacies. When Aetna indicated it intended to perform a market check, in order to decide if it would contract with a PBM offering lower drug prices, as it is permitted to do under the CaremarkPCS Health contract, the Caremark negotiators immediately offered to lower Aetna's drug prices by 100 bps, starting in September, 2013, and going forward. When Aetna actually commenced the market check, the Caremark defendants offered to improve Aetna's drug prices for 2014 by 150 bps.

113. These immediate, unilateral offers of lower prices would not have been likely if the Caremark defendants were truly passing along the actual drug prices that had been negotiated with the pharmacies since the Caremark defendants should not have had those additional savings "in pocket" to offer to Aetna.

114. During the first half of 2013, the Caremark defendants again announced MAC price increases. Caremark baldly asserted that this was being done to ensure that the Caremark defendants would "hit," but not exceed, the discount guarantee. Hence the "Medicare MAC Change Notification" to Aetna listed the following justification for every MAC change -- "Adjustment to the MAC list intended to manage and allow CMX [Caremark] to achieve the contract guarantees." Since these were price *increases*, not decreases, the changes could only serve to ensure that the Caremark defendants did not exceed the price guarantee.

115. At this time also, various Aetna personnel commented about the apparent spread that the Caremark defendants were improperly embedding in their reported prices. Nancy Cocozza, Head of Medicare for Legacy/Coventry (a subsidiary of Aetna), in discussions with other Aetna personnel, questioned why the Caremark defendants were balking about giving Aetna

control of MACs since Caremark could not earn a spread anyway – "I also explained that the CMS pass through pricing rules for Medicare preclude CVS Caremark from hiding spread, and because of that, they should not prohibit us from negotiating retail arrangements or controlling MAC. If they can't earn spread, why should it be an issue?"

116. Terri Swanson continued to comment on the "hidden spread" inherent in the generic discount rate guarantee, in an email dated July 28, 2013: "look at how much CVS CM is making today on our arrangement – including the hidden spread inherent in the capped generic discount rate guarantee." In emails discussing the possibility of different timing of the announced MAC price increases, Swanson also matter-of-factly stated that CVS is "managing to the guarantee" so it shouldn't care what the slope of the GER discount looks like over the course of the year.

117. In negotiations for a new contract following the market check, the Caremark defendants offered a risk share provision as follows: If Caremark acquisition costs accelerated faster than the Part D discount guarantees in the agreement, Caremark would reset the guarantee so that Aetna would receive 75% of the improvement. This, too, indicates that Caremark was operating the PBM so as to make a spread on the difference between the price Caremark paid the pharmacies and the price Aetna was charged for the drugs because otherwise Aetna would receive 100% of the improvement.

118. In response to this proposal, Relator Behnke advised the Caremark defendants that the 25% Caremark retained in this type of split would create an administrative cost that would have to be reported to CMS. Tellingly, Caremark then stated it would no longer offer the split it had proposed.

119. The contract between Aetna and the Caremark defendants also guarantees Aetna confidential lower prices for the identical generic drugs if they are dispensed to Aetna large commercial non-Part D retail plans with lock in pricing:

MAC and Non-MAC Combined Retail Discount Guarantees for Qualifying Generic Prescriptions at Retail												
Days Supply	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**
1-34	N/A	75.20%	75.40%	75.60%	75.80%	76.00%	76.20%	76.40%	76.60%	76.80%	77.00%	77.20%
35-83	N/A	75.20%	75.40%	75.60%	75.80%	76.00%	76.20%	76.40%	76.60%	76.80%	77.00%	77.20%
84+	N/A	75.20%	75.40%	75.60%	75.80%	76.00%	76.20%	76.40%	76.60%	76.80%	77.00%	77.20%

Although the discounts look quite comparable to those for the Medicare Part D business, there is a significant difference on the commercial side. Under the contract, "for the avoidance of any doubt no Administrative Fees shall be payable with respect to Claims subject to Commercial Retail Large Account Lock-In Pricing." Rather the administrative fee is part of the amount Aetna pays for the drug pursuant to the discount guarantee.

Since the Caremark defendants were clearly not providing their PBM services for free on the commercial side, it is apparent that the Caremark defendants had negotiated lower drug prices for Aetna's large retail commercial plans or were charging Aetna lower drug prices for the large commercial plans. Since Aetna is actually paying Caremark slightly less for drugs on the commercial side (getting a 75.20% discount off AWP, or paying 24.8% instead of 25%), and Aetna is not paying the $1/scrip administrative fee, it is obvious that the Caremark defendants are paying the pharmacies less than the amount that Aetna is paying Caremark, because otherwise the Caremark defendants would not be making any money on their services.

120. For each of the years 2011-2013, the reported Medicare Part D prices received by Aetna from the Caremark defendants matched the contract guarantee exactly. This result would

only be expected from a lock-in contract. It would not occur if true pass-through prices were being reported.

121. The information set forth in each of the paragraphs 92 to 120 above demonstrates that the Caremark defendants are earning a "spread" or the difference between what Caremark pays pharmacies in the Aetna network and what the Caremark defendants report to Aetna to report to CMS as the negotiated price for drugs for Part D beneficiaries, contrary to the Medicare Part D regulations.

122. On information and belief, the Caremark defendants had an agreement with the pharmacies in the Aetna network that resulted in the actual price paid for the Part D prescription being the average of the commercial and the Part D price for the same drug. In other words, the Caremark defendants negotiated a swapping arrangement whereby the pharmacies received a higher payment for Part D prescriptions in exchange for accepting lower payments for commercial contracts. In addition, or alternatively, on information and belief, the Caremark defendants failed to report certain post-point-of-sale adjustments, fees or payments they received that lowered the drug cost actually paid.

B. Additional Evidence That the Caremark Defendants are Not Reporting True Pass-Through Prices to Aetna for Reporting to CMS

123. At the time of filing, CVS Caremark is the largest purchaser of drugs in the country. Indeed, CVS Caremark claimed to provide Aetna with "industry leading pharmacy benefit managing services" and stated that Caremark is "unmatched in terms of the . . . low total cost" it delivers including negotiated rates for generic drugs. Given its market share, as well as the size of the Aetna Part D plans, there is no reason CVS Caremark and the Caremark defendants should not be able to negotiate for Aetna the lower drug prices reflected in the prices that Aetna's competitors were reporting.

124. Additionally, the prices Part D Sponsors pay for drugs usually vary by pharmacy chain or from geographic region to region, reflecting regional variations in costs and common price differentials between large national chains as compared to small, local pharmacies. Inexplicably, the discounts from AWP that the Caremark defendants say they have negotiated with pharmacy chains for Aetna's Part D beneficiaries do not vary at all by geographic region or pharmacy chain. For example:

OHIO					
	CVS	**Rite-Aid**	**Target**	**Walgreens**	**Walmart**
Wellcare Health Classics Plan	81.7	83.2	83.8	83.5	85.0
RCGM Plus	85.4	82.6	82.6	85.9	74.6
Aetna	80.8	80.8	80.8	80.8	80.8

NEW YORK					
	CVS	**Rite-Aid**	**Target**	**Walgreens**	**Walmart**
Wellcare Health Classics Plan	81.7	83.2	83.9	83.7	85.0
RCGM Plus	85.4	82.6	82.6	85.4	74.6
Aetna	80.7	80.8	80.8	80.8	80.8

NEW JERSEY					
	CVS	**Rite-Aid**	**Target**	**Walgreens**	**Walmart**
Wellcare Health Classics Plan	81.7	83.2	83.7	83.7	85.0
RCGM Plus	85.4	82.6	82.6	85.5	74.6
Aetna	80.8	80.8	80.8	80.8	80.8

Thus the prices Aetna's Part D plans pay for drugs through the Caremark defendants PBM do not vary based on the size of the pharmacy chain, suggesting that those prices are not the actual prices that the Caremark defendants have negotiated with the pharmacies. These prices are consistent with lock-in prices, not the pass through prices the Caremark defendants were supposed to provide.

C. Caremark's False Certification to Aetna of Negotiated Prices

125. Aetna, in reliance on information received from, reviewed by and approved by the Caremark defendants, reported the drug cost data and negotiated prices it received from the Caremark defendants on each PDE submitted for its Part D plan beneficiaries from January 1, 2011 through December 31, 2014. Aetna also relied on a certification it received from CaremarkPCS Health and on information it received from the Caremark defendants for DIR reports that did not reflect network management fees or other price concessions received by the Caremark defendants. Accordingly, as a result of the Caremark defendants' actions, the price concessions or network management fees were not factored into the DIR reconciliation reports.

126. CMS used the negotiated prices and drug cost data submitted on behalf of Aetna to reconcile payments made or due to Aetna for drugs dispensed to Aetna beneficiaries in 2011, 2012, 2013 and 2014.

127. As a result of this reconciliation, Aetna received payments from CMS in the years 2012 and 2013.

128. Had the Caremark defendants provided accurate, non-fraudulent negotiated prices to be reported to CMS, the amount of these payments from CMS would have been lower by an amount estimated to be $25 million in 2012 and $50 million in 2013.

D. The Caremark Defendants Report False Negotiated Prices for their Affiliated Part D Plan, Silverscript

129. A Caremark subsidiary is the PBM for SilverScript. This PBM or the Caremark defendants negotiate with pharmacies the drug prices SilverScript beneficiaries pay. At the time of filing, the prices paid for drugs for SilverScript beneficiaries are 25% higher than those reported by competing PDPs. These prices are essentially the same or slightly higher than the prices reported for Aetna. These prices are consistent with lock-in prices, and a hidden spread, not the

pass through prices the Caremark Defendants were supposed to provide. Further, the discounts from AWP that the Caremark defendants say they have negotiated with pharmacy chains for Silverscript's Part D beneficiaries do not vary at all by geographic region or pharmacy chain suggesting that those prices are not the actual prices that the Caremark defendants have negotiated with the pharmacies.

130. Upon information and belief, the Caremark defendants have negotiated lower prices for drugs with the pharmacies in the SilverScript network than those it reported or caused to be reported to CMS on PDEs submitted on behalf of or by SilverScript.

131. The prices reported by the Caremark defendants and/or SilverScript were not the amount actually paid. On information and belief, the Caremark defendants had an agreement with the pharmacies in the SilverScript network that resulted in the actual price paid for the generic Part D prescription drugs being the average of the commercial and the Part D price for the same drug. In other words, the Caremark defendants negotiated a swapping arrangement whereby the pharmacies received a higher payment for Part D prescriptions in exchange for accepting lower payments for commercial contracts.

132. Upon information and belief, the Caremark defendants and SilverScript failed to report certain post-point-of-sale adjustments, fees or payments received by Caremark that lowered the drug cost actually paid.

133. Upon information and belief, the Caremark defendants and SilverScript do not accurately report drug costs and drug cost data on SilverScript PDEs. As a result, the Federal Government's payments to SilverScript under Part D, including those for low income subsidies for SilverScript beneficiaries, have been increased. Relator estimates that the Caremark defendants

causing Silverscript's to report fraudulent negotiated prices resulted in an overcharge to the government of $215 million in 2012 and $310 million in 2013.

134. On information and belief, the Caremark defendants are negotiating an aggregate price guarantee for SilverScript with each pharmacy chain in its network. In other words, each chain agrees to accept in payment a percentage off of AWP per generic drug, measured across the commercial plans and Part D plans for which the Caremark defendants are the PBM.

135. SilverScript and the Caremark defendants have made explicit certifications of the accuracy and completeness of PDE data since 2006. They continue to make these certifications on an ongoing basis to the Government.

136. SilverScript and the Caremark defendants have provided or caused to be provided to the government certifications of data accuracy, completeness and truthfulness and the acknowledgments that the claims data will be used for the purpose of obtaining federal reimbursement required by 42 C.F.R. § 423.505(k)(3) that are false and fraudulent.

137. Relator estimates that, as a result of the activities outlined in paragraphs 92 to 136, the Caremark defendants have hidden approximately $500 million of administrative expense in drug cost in 2012, approximately $900 million in 2013 and will hide$1.5 billion of administrative expense in drug cost in 2014.

E. The Caremark Defendants Fraudulently Concealed and Reduced the Amount of Money Owed to CMS Through the Year-End Reconciliation Process

138. In addition to causing the Government to overpay, as discussed above, the conduct described also or alternatively damaged the Government by causing it to receive less in year-end reconciliation payments from Part D Sponsors. That is, the Caremark Defendants caused the Part D Sponsors to report inaccurate prices through PDEs and DIR submissions. The false PDEs and

DIR submissions skewed the year-end reconciliation process, as described below in more detail, causing the Part D Sponsors either to fail to pay back money owed to the Government or collect more than they were entitled to collect.

139. This year-end reconciliation process imposes an automatic, affirmative obligation to pay back money to the Government if it is determined based on the PDEs and DIR submissions that the Government paid too much through its monthly prospective payments during the year, that is, that the bid estimate of drug costs turned out to be higher than the actually paid drug costs. Whether money is owed to the Government or paid back to the Part D Sponsor is a matter of whether the monthly prospective payments based on the bid exceeded or failed to meet the actually paid drug costs that are calculated at year end.

140. By way of background, a Part D Plan sponsor submits an annual bid to CMS, including a per member per month ("PMPM") cost estimate by the Plan to provide Part D benefits to a Medicare beneficiary in the applicable geographic area.

141. As described above (e.g., paragraphs 36-37, 51), a Part D sponsor receives prospective monthly payments from CMS through Direct, Reinsurance and Low Income Copay subsidies ("LICS") based on the Plan's standardized bid, risk-adjusted for health status and other factors. 42 C.F.R. §§ 423.315, 423.329.

142. Also as described above (paragraph 69), there is a year-end reconciliation process to determine whether CMS owes the Part D Sponsor additional payments, or the Part D Sponsor has to pay money back. After receiving the final, required PDE and DIR submissions, CMS reconciles payments received by a Part D Plan Sponsor to determine whether additional funds are due to, or recoverable from, the Part D Plan Sponsor. 42 C.F.R. § 423.343(c), (d) (describing how

CMS either makes payments to Plan sponsors or recovers payments from them); 42 C.F.R. § 423.352 (reconciliation done after receipt of required PDE and DIR submissions).

143. Specifically, following the end of a year, the prospective Reinsurance and LICS payments are reconciled to match the estimated drug costs in the bid to the actually paid drug costs. This is done using reported data that was submitted through PDE and DIR reporting. If the estimated Reinsurance and LICS payments made throughout the year exceeded the actual costs, the Part D Sponsor is obligated to pay back that amount to CMS.

144. In addition, at year end and as a final step in the reconciliation process, CMS applies a fixed, statutory formula for risk-sharing with respect to the prospectively-paid Direct Subsidy amounts. That is, the Direct Subsidy is subject to a Risk-Sharing arrangement capping the profits or losses of the Plan. 42 C.F.R. § 423.336, § 423.343. If a Plan Sponsor's actually paid drug costs exceed the estimated costs that were incorporated into the bid by more than 5%, the Plan will recoup some of those losses through a pre-set, statutory risk-sharing arrangement with CMS. Conversely, if the Plan Sponsor's estimated costs *exceed* its actually paid drug costs by more than 5%, the Sponsor is obligated to *pay back to CMS* some portion of the estimated payments the Plan had received on a prospective basis from CMS. The calculation of the Risk-Share outcome is based on information submitted through both PDEs and DIR reporting.

145. Thus, the year-end reconciliation process compares the actually paid drug costs to the bid estimate (that drives the monthly prospective payments throughout the year). Depending on whether the actually paid drug costs are less than, or greater than, the bid estimate determines the flow of funds that results from the reconciliation process, that is, whether the Part D Sponsor is eligible for additional payments from CMS at year-end or owes money back to CMS. Either

way, these are fixed payments or obligations, automatically and mathematically calculated based on the variance of the bid from actually paid drug costs.

146. Because both Aetna and SilverScript, as Plan sponsors, submitted separate bids for hundreds of plans every year, some Plans received overpayments and owed money back to the Government as a result of the reconciliation process and other Plans had been underpaid and received payments from the Government. In both cases, the alleged fraud impacted the amounts – of either the repayments owed or the amounts wrongly received. Where the Plan had been overpaid, and owed money back to the Government, the false PDEs and DIR reports were material to an obligation to pay money to the Government or to conceal, avoid or decrease an obligation to pay money to the Government, in violation of 31 U.S.C. § 3729(a)(1)(G).

147. The bid estimate process contemplates that roughly half of plans will owe money back to CMS and roughly half of plans will receive additional payments. Based on her substantial involvement every year in preparing bid estimates for Aetna's Part D plans and follow-up to see whether plans received money back or owed money at the end of the year, Relator is aware that in every year between 2011 and 2015 some, and most likely a substantial number of, Aetna plans owed money back to CMS following the year end reconciliation process. Had accurate drug price information been submitted to CMS, the amounts owed would have been higher.

148. Similarly, for SilverScript, it is virtually certain that some Plans would owe money back to CMS for some years, and some Plans would have additional money paid to them. For example, there were substantial amounts owed back to CMS from all SilverScript plans, in the aggregate, for each of the years 2011 through 2013, for risk-share reconciliations alone. http://medpac.gov/docs/default-source/reports/chapter-6-sharing-risk-in-medicare-part-d-june-2015-report-.pdf?sfvrsn=0. These aggregate overpayments could only exist if at least some plans

had received overpayments and thus owed money back. Had accurate prices been submitted to CMS, the amounts owed would have been higher.

149. When a Plan Sponsors' reported drug prices are fraudulently inflated, the costs appear to be higher than they actually were (or the "actually paid" drug costs are inflated). If the Plan's estimated drug costs in the bid turn out to have been high, such that it was going to owe money back to CMS at year-end, the inflated reported prices would reduce the amount that the Plan would owe back to CMS. These are reverse false claims, where the Plan or the PBM has fraudulently reduced the amount of money that the Plan owes back to the government.

150. If the estimated drug costs in the bid had been low as compared to actually paid drug costs, then the inflated reported prices would increase the amount that the Plan will be able to recover from CMS at year-end.

151. Regardless of the accuracy of the bid estimate of drug costs, reporting fraudulently inflated drug prices impacts the reconciliation and risk-share payments at year end, always to the benefit of the Plan and at the expense of CMS. This occurs whether the fraudulent reporting was at the PDE or DIR stage. Knowing falsity at either stage is actionable under the FCA.

F. Failure to Charge the Negotiated Price Adversely Impacts the Beneficiary and Ultimately Causes the Government to Pay More

152. The negotiated price is the amount that is supposed to be charged to the Part D plan beneficiary for drugs. The beneficiary does not pay for any administrative cost.

153. As CMS explained when first considering the change to negotiated pricing:

> [We are] refining our definitions related to what may be included in the drug costs Part D sponsors use as the basis for calculating beneficiary cost sharing, reporting drug costs to CMS for the purposes of reinsurance reconciliation and risk sharing, as well as submitting bids to CMS.
>
> Medicare Program: Revisions to the Medicare Advantage and Prescription Drug Benefit Programs: Proposed Rule, 73 Fed. Reg. 28556 (May 16, 2008)

154. As CMS recently explained in discussing whether certain costs should be backed out of reported (negotiated) prices and instead reflected in aggregate, annual reconciliations (typically, DIR), the "reporting differential matters because this variation in the treatment of costs and price concessions affects beneficiary cost sharing, CMS payments to plans, federal reinsurance and low-income cost-sharing (LICS) subsidies, and manufacturer coverage gap discount payments. Differential treatment of costs would also be expected to affect plan bids." *Medicare Program: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program*, 42 CFR Parts 409, 417, 422, 423 and 424 [CMS-4159-P], at p 234.

155. Further, when price concessions "from pharmacies are reflected in forms other than the negotiated price, the degree of price concession that the pharmacy has agreed to is no longer reflected in the negotiated prices available at point of sale or reflected on the Medicare Prescription Drug Plan Finder (Plan Finder) tool. Thus, the true price of drugs at individual pharmacies is no longer transparent to the market. Consequently, consumers cannot efficiently minimize both their costs (cost sharing) and costs to the taxpayers by seeking and finding the lowest-cost drug/pharmacy combination. Moreover, as the coverage gap closes, there are fewer and fewer beneficiaries who are exposed to the full cost of drug products, either at the point of sale or as reflected in Plan Finder estimates. When this occurs, the basis of competition shifts from prices to cost sharing, and the pricing signals available to the market can be distorted when lower cost sharing is not aligned with lower prices. Thus, we believe the exclusion of pharmacy price concessions from the negotiated price thwarts the very price competition that the Congress intended when it said that private plans would compete with other plans on both premiums and negotiated prices.," *id*., at p. 237.

156. Any reporting of negotiated prices that excludes such costs – especially where those costs are not even accounted for in the post-sale reconciliation through DIR, as here – creates these issues on an even greater scale.

157. Through their negotiations with pharmacies, the Caremark defendants caused the pharmacies in its network to fail to charge beneficiaries of the Aetna PDPs the true negotiated price. Instead, such beneficiaries were charged higher prices. As a result, beneficiaries paid higher co-pays and deductibles and were pushed earlier into the coverage gap phase (the "donut hole") and also the catastrophic phase where the government pays most of the total cost.

158. In addition, by failing to reveal the hidden administrative costs related to the Aetna contract, or the amounts that were actually paid to pharmacies for drugs dispensed to Aetna and SilverScript beneficiaries, the Caremark defendants caused increases in the low income subsidy payments and reinsurance subsidy payments made by the government, the very results that Congress and the regulations intended to prevent. *See* 74 Federal Register 1494 at 1505.

159. Failure to offer a beneficiary the negotiated price of a Part D drug constitutes fraud. CMS Prescription Drug Benefit Manual, chapter 70.1. 3 (p. 59) (2006 ed).

VI. OTHER SILVERSCRIPT BENEFITS FROM THE FALSE REPORTING OF DRUG PRICES ACTUALLY PAID

160. At the time of filing, Aetna and SilverScript were the largest Part D clients of CVS Caremark's PBMs. Together they totaled 70% of CVS Caremark's Medicare beneficiaries.

161. CVS Caremark reported in its 10Q filed on October 17, 2013, that as of June 30, 2013, SilverScript had approximately 3.4 million members.

162. SilverScript has the largest number of members of any Part D plan in the country who are eligible for the low-income subsidy whereby the government pays most of the Part D premium, deductibles and cost sharing. Indeed, 25% of all Part D beneficiaries who qualify for

the low-income subsidy are SilverScript members, see http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/LIS-Enrollment-by-Plan.html

163. The Federal Government pays approximately 18% of the drug cost of Medicare Part D for non-low income beneficiaries. The Federal Government pays 65% of the drug cost of Medicare Part D for each beneficiary receiving the low-income benefit. For 2013, Medicare estimated it would pay private plans $1,139 in reimbursements per enrollee and an additional $2,134 per low-income enrollee. 2012 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, April 23, 2012, p. 167, available at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2012.pdf. Therefore, it benefits Silverscript and also Caremark if its reported drug prices are high, as the Federal Government will pay 65% of the cost.

164. Hiding administrative costs by reporting higher negotiated drug prices enables SilverScript to lower the premiums in its Part D bids. Amounts included in the reported negotiated drug prices that are administrative costs should not be included in these bids.

165. Hiding administrative costs in the false negotiated drug prices that were reported allows SilverScript to qualify for auto-enrollment and facilitates auto-enrollment of more low-income subsidy eligible individuals as the SilverScript premiums do not exceed the low income subsidy amount, *see*, 42 C.F.R. 423.34 (d).

VII. KICKBACKS BY THE CAREMARK DEFENDANTS

166. Paragraphs 1 to 165 are incorporated by reference as if fully set forth.

167. CVS Caremark is one of the three largest PBMs operators in the United States. CVS Caremark has one contract ("the commercial contract") with each pharmacy chain. That contract covers all the different commercial lines of business CVS Caremark has with that chain

such as providing prescriptions for commercial plans and workers' compensation programs. This contract includes different prices for participation in preferred and contract networks for clients of CVS Caremark's PBMs.

168. Upon information and belief, CVS Caremark has a separate contract for pharmacies in its network which participate in Medicare Part D.

169. The drug prices the Caremark defendants pay to pharmacies pursuant to commercial contracts are lower than the prices the Caremark defendants negotiate and pay to pharmacies for the identical drug under Medicare Part D. This is demonstrated in the Caremark defendants' contract with Aetna, where commercial prices are lower and where Aetna is *not* charged an administrative fee (the $1 per prescription) referenced in ¶ 97, above).

170. This arrangement benefits the Caremark defendants because in commercial contracts, they keep the difference ("the spread") between the price Caremark has negotiated with the pharmacy and the price they charge their PBM customers, particularly under lock-in PBM agreements. For example, if the commercial customer agrees to pay $10 per prescription of Drug X, the Caremark defendants negotiate a price of $7 with the pharmacy for the drug and keep the $3 difference. However, the Caremark defendant tells the commercial customer that the price paid for the drug was $10. The Caremark defendants can also keep the spread related to their commercial contracts by manipulation of MACs.

171. As set forth in paragraphs 57 to 70, Medicare Part D seeks pass-through pricing and will not pay this spread as part of the drug cost. On information and belief, the Caremark defendants therefore negotiate with and agree to pay the pharmacy $10 as the ingredient cost for the same drug dispensed to a Medicare beneficiary.

172. Because the Part D program is paying more for the same drug, the Caremark defendants can keep a large administrative fee from their commercial plans. The pharmacy is satisfied with this arrangement because, on average across all commercial and Part D plans, it is receiving its desired price for each drug. For example, Chain A wishes to be paid $9, on average for a particular drug. The Caremark defendants in their role as a PBM allegedly negotiate a $10 point of sale price for the drug when it is dispensed to a Part D beneficiary. The Caremark defendants also agree to pay the pharmacy $8 for the same drug dispensed under a commercial drug plan. The Caremark defendants then communicate to the commercial customer (with a lock in contract), that the price of the drug is $10, but keep the $2 difference ($10-8) as an administrative fee. On average, the pharmacy has received $9 for the drug.

173. On information and belief, the Caremark defendants are negotiating an aggregate price guarantee with each pharmacy chain in their networks. In other words, each chain agrees to accept in payment, a percentage off of AWP per generic drug, measured across the commercial plans and Part D plans for which the Caremark defendant is the PBM.

174. On information and belief, the Caremark defendants, directly or indirectly, agree to accept pharmacy chains into their commercial networks if the pharmacy chain agrees to an arrangement that charges lower drug prices for commercial plan participants and higher prices for the same generic drugs dispensed to Part D plan participants.

175. In addition to the benefits or increased revenues already described above, to the extent an Aetna Part D beneficiary or SilverScript beneficiary fills his prescription at a CVS pharmacy, CVS Caremark benefits further from the inflated reported price, because the CVS pharmacy will be paid the higher false price reported to CMS.

VIII. APPLICABLE LAW

A. The Federal False Claims Act

176. The Federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, provides, *inter alia*, that any person who (1) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," (2) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," is liable to the United States for a civil monetary penalty plus treble damages; or (3) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government. 31 U.S.C. § 3729(a)(1)(A)-(B) and (G).

177. The terms "knowing" and "knowingly" are defined to mean "that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A)(i)-(iii). Proof of specific intent to defraud is not required. 31 U.S.C. § 3729(b)(1)(B).

178. The term "claim" means "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (1) is presented to an officer, employee, or agent of the United States; (2) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Governments behalf or to advance a Government program or interest, and if the United States Government (a) provides or has provided any portion of the money or property requested or demanded; or (b) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded …." 31 U.S.C. § 3729(b)(2)(A)(i)-(ii).

179. The term "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

B. The Federal Anti-Kickback Statute

180. The federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that remuneration provided to those who can influence healthcare decisions would result in goods and services being provided that are medically unnecessary, of poor quality, or harmful to a vulnerable patient population. To protect the Medicare and Medicaid programs from these harms, Congress enacted a prohibition against the payment of kickbacks in any form. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

181. The AKS prohibits any person or entity from offering, making, soliciting, or accepting remuneration, in cash or in kind, directly or indirectly, to induce or reward any person for purchasing, ordering, or recommending or arranging for the purchasing or ordering of federally-funded medical goods or services:

> whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both. 42 U.S.C.

§ 1320a-7b(b). Violation of the statute also can subject the perpetrator to exclusion from participation in federal health care programs and, effective August 6, 1997, civil monetary penalties of $50,000 per violation and three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

COUNT I
FEDERAL FALSE CLAIMS ACT
31 U.S.C. §§ 3729(A)(1)(A)

182. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

183. At all relevant times to this Complaint, Defendants knowingly presented, or caused to be presented, directly or in directly false and fraudulent claims for or approval to the United States.

184. By virtue of the false or fraudulent claims presented or caused to be presented by the Defendants, the United States suffered and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT II
FEDERAL FALSE CLAIMS ACT
31 U.S.C. §§ 3729(A)(1)(B)

185. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

186. At all times relevant to this Complaint, defendants knowingly made, used, or caused to be made or used, false records or statements material to false or fraudulent claims to the United States and false records or statements to get false claims paid.

187. By virtue of the false or fraudulent claims presented by the Defendants, the United States suffered damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT III
FEDERAL FALSE CLAIMS ACT
31 U.S.C. §§ 3729(A)(1)(G)

188. Relator re-alleges and incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

189. Defendants knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the United States in violation of 31 U.S.C. § 3729(a)(1)(G).

PRAYER FOR RELIEF

WHEREFORE, Relator, on behalf of the United States, demands that judgment be entered in her favor and against Defendants for the maximum amount of damages and such other relief as the Court may deem appropriate on each Count. This includes, with respect to the Federal False Claims Act, three times the amount of damages to the Federal Government plus civil penalties of no more than Eleven Thousand Dollars ($11,000.00) and no less than Five Thousand Five Hundred Dollars ($5,500.00) for each false claim, any other recoveries or relief provided for under the Federal False Claims Act, and such other relief as the Court deems just and appropriate.

Further, Relator requests that she receive the maximum amount permitted by law of the proceeds of this action or settlement of this action collected by the United States, plus reasonable expenses necessarily incurred, and reasonable attorneys' fees and costs. Relator requests that her award be based upon the total value recovered, both tangible and intangible, including any amounts received from individuals or entities not parties to this action.

Dated: November 10, 2020

/s/ Susan Schneider Thomas
Susan Schneider Thomas

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